

Notice of Allowability

Application No.

10/759,477

Examiner

Melanie J. Hand

Applicant(s)

LAHERTY ET AL.

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed February 13, 2006.
2. ☒ The allowed claim(s) is/are 1-26.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

MJH

REASONS FOR ALLOWANCE

Response to Arguments

Applicant's arguments, see Remarks, filed February 13, 2006, with respect to the rejection of claims 1-17 under 35 U.S.C. 102 and the rejection of claims 18-21 under 35 U.S.C. 103 have been fully considered and are persuasive. The rejections of claims 1-21 have been withdrawn.

Allowable Subject Matter

Claims 1-26 are allowed.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: A thorough search of the prior art of record did not disclose any reference, alone or in combination with other reference(s) that teaches or fairly suggests any of the following: a device for use in assisting in inserting a catheter in a female comprising a pair of legs extending outwardly from the main body portion wherein a flange extends longitudinally along each of the legs (Claim 1), having a catheter guide in the form of an opening located between said legs (Claims 10, 17), or a method of inserting a catheter in a female comprising the step of providing a device having a pair of flanges configured to spread the labia of the female, and inserting a catheter in an opening between said flanges (Claim 18).

The closest prior art of record is U.S. Patent No. 4,911,698 to Wapner and U.S. Patent No. 6,461,340 to Lenker et al. Wapner teaches an intra-labial device for hygienically obtaining a urine specimen from a female. Wapner teaches that the device has a hollow body with an upper

receiving end and a lower discharge end. Vertical sidewalls sealingly engage the labia minora, and there is a finger grip. Wapner teaches that this device contains a spigot for directing the flow of urine from the urethral canal outward to a receptacle and that the device has an opening to accept the flow of urine, and that flow is subsequently directed through the spigot. Wapner does not teach that the vertical sidewalls define legs or flanges that separate to define an opening through which a catheter is capable of being inserted. Further, it would not be obvious to one of ordinary skill in the art to use the device of Wapner with a catheter as the spigot is not configured to engage a catheter or allow it to progress to the urethral canal in such a manner as to allow the user to ensure proper engagement and positioning of the catheter in the urethral canal. Since Wapner does not teach the device set forth in claims 1, 10 and 17, Wapner therefore also does not teach a method comprising the step of providing a device that is configured to accept a catheter through an opening between two legs having flanges extending therefrom, and therefore also does not teach any of the subsequent steps set forth in claim 18.

Lenker teaches a urinary incontinence device that has laterally extending projections that engage the labia minora in a spreaded configuration, defining two "legs" with flange portions extending therefrom. However, since Lenker teaches an incontinence device, said device occludes the urethral canal instead of providing access to it in the form of an opening configured to allow a catheter to be placed properly in the urethral canal. Lenker thus does not teach an opening between said wings to accept a catheter, and also does not teach a method for inserting any catheter. It would not be obvious to one of ordinary skill in the art therefore to modify the device by creating an opening to accept a catheter. Any modification that would allow a catheter to be inserted would destroy the function of the device of Lenker.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the

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issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

